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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,800	REIF ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *21-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/31/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. The examiner of the instant application has changed. Please direct all future correspondence to Primary Examiner Cherie M. Woodward, Art Unit 1647. Additional contact information is provided at the end of the Office Action.

2. Applicant's Response filed 8/17/2010 are acknowledged and entered. Claims 1-32 are pending. Claims 21-32 are withdrawn pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention. Claims 1-20 are under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 8/31/2010 has been considered by the examiner. Except as otherwise noted, only English-language abstracts of foreign references have been considered. A signed copy is attached.

Response to Arguments

Rejections Maintained

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-2, 7, 12, 13-15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29922585, Beam (WO 02/083194) and Starling et al (US 6,210,715, issued: 4/3/2001), for the reasons of record and the reasons set forth herein.

Applicant argues that the instant rejection is conclusory, that the optimization is speculative and without support of record (Remarks, p. 2). Applicant argues that Starling does not cure the deficiencies of DE '585 or Beam (Remarks, p. 2). Applicant argues that the DE '585 and Beam do not limit the interconnecting pore share in the porosity to pore sizes less than 10μm and that the references require macropores to be the interconnecting pores, this teaching away from the instant invention (Remarks, pp. 2-3). Applicant argues that there is no evidence of record to support the assertion that modifying interconnecting pore size is a known means of optimizing the composition (Remarks, p. 3). Applicant argues that it would not have been obvious in the art to modify the interconnecting pore size in a manner that is contrary to the express disclosure of DE '585 and that there would be no reasonable expectation of success of doing so (Remarks, p. 3). Applicant argues that the absence of the interconnecting macropores of DE '585 would not be effective for the intended use of DE '585 because the modification would not enable the rapid bony in-growth desired by DE '585 (Remarks, p. 3).

Applicant argues that the Action provides no evidence, rationale, or reasonable expectation of success that claimed particle size is a known means for optimizing a bone growth implant (Remarks, p. 4). Applicant argues that there is no evidence to support the assertion that the shape is a preferential choice which can be optimized (Remarks, p. 4).

Applicant argues that there is no motivation to modify or combine DE '585 and Beam (Remarks, p. 4). Applicant argues that Beam does not disclose granules or shaped particles formed from granules having the claimed statistical distributed porosity with the pore size ranges of claim 1 and Beam does not disclose interconnecting pores where the pore size is less than10μm (Remarks, p. 4). Applicant argues that it would technically not be possible to modify the filler of DE '585 according to Beam to achieve an isotropic structure because Beam does not disclose granules or shaped articles formed from granules having a statistically distributed porosity with the discrete pore size ranges claimed (Remarks, p. 5).

Applicant argues that Starling provides no suggestion that changing the pore sizes is a known means of optimizing the pore size and that there is no suggestion in Starling to modify the pore size in a manner contrary to DE '585 (Remarks, pp. 5-6). Applicant argues that even though Starling discloses that various process steps have an effect on the pore size does not render the claimed invention obvious because Starling does not teach the desirability of modifying the pore size (Remarks, p. 6). Applicant argues that Starling teaches away from the claimed invention by disclosing pore sizes of 350μm to 500μm (Remarks, p. 6). Applicant argues that Starling discloses a coating to provide an increase in the chemical activity of the microbeads due to the higher surface area to the large interconnecting pore size in the coating forming porous channels to accommodate cell and tissue in-growth (Remarks, p. 6). Applicant argues that the open porosity in Starling is limited to a single pore size in contrast to the claimed invention, having at least two discrete pore sizes (Remarks, p, 7). Applicant argues that Starling does not disclose a bone formation agent without interconnecting macropores (Remarks, p. 7). Applicant argues that the combination of the references would not produce an bone formation agent having the instant claim limitations (Remarks, p. 7).

Applicant's arguments have been fully considered, but they are not persuasive. As previously stated of record, with regard to the limitations of claim 1, reciting that the interconnected pore share in the porosity is limited to pore sizes less than 10um, the variability of interconnected pores (which the examiner reads as "channels") in terms of size and connectivity (interconnectedness) is routinely altered by changes in sintering temperature, as taught by the '715 patent (Starling) (see Office Action mailed 5/21/2010 at pp. 5-6). Accordingly, Applicant's arguments that the rejection is conclusory, that the optimization is speculative and without support of record, is entirely without merit. As plainly and unambiguously stated of record, changes in sintering temperatures to effect a more highly closed-porosity composition with fewer and smaller interconnected pores (channels) is taught by Starling patent in Examples 3, 6, and 10. These sintering temperature ranges are taught in the instant specification at p.15. Temperatures are results-effective variables which can be optimized. In the case of adjusting the sintering temperature to effect a more dense composition with smaller pore sizes and interconnected pore (channel) sizes, one of skill in the art would clearly recognize that the sintering temperatures can be variable and could easily be optimized by one of ordinary skill in the art based on the need to affect pore size, channel size, and density of pores and channels, such that the composition comprises a more open or closed porosity, as expressly taught by the '715 patent. In the instant case, optimization of sintering temperature to affect these physical compositional changes would amount to nothing more than routine experimentation that can be optimized. See *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977), *In*

re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980), *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969), *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989) (cert. denied, 493 U.S. 975 (1989)), *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990), *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997), and MPEP 2144.05.

In arguing that it would not have been obvious in the art to modify the interconnecting pore size in a manner that is contrary to the express disclosure of DE '585 and that there would be no reasonable expectation of success of doing so, Applicant overlooks the fact that the instant rejection is a combinatorial rejection. One of ordinary skill in the art would have reasonably known, based on the express teachings of Starling, that pore sizes and porosity could readily be adjusted depending on the needs of the application and the desire for a composition with fewer and smaller interconnected pores.

The rationale for combining the three references to create the composition comes expressly from the references themselves. Applicant's arguments are directed to some embodiments of the references while ignoring others. DE '585 teaches that microporous bone prosthesis materials comprising particles of porous calcium phosphate that have open cells equal to or greater than 0.01μm and smaller than 10μm with a total porosity of up to 90% are well known in the art (p. 3). DE '585 also teaches that bone replacement material is known in the prior art that has a porosity of 40-90% where largely spherical pores range from 3-600μm in size and are joined to each other and to the surface of molded bodies by additional capillary pore channels having a diameter of 1-30μm (p. 3). These additional pore channels may be achieved by the addition of organic fibers to the staring mixture (p. 3). Without the addition of the organic fibers, the interconnectedness of the pores would be innately limited based on the physical properties of the composition. All one need do to reduce and all but negate the connected channels would be to not add organic fibers that would create the channels, thereby creating an interconnected pore share where the porosity is extremely limited. Based on the express teachings of DE '585, the degree of interconnectedness of pore share (i.e. channels) is old, well-known, and routinely optimized based on adding or not adding organic fibers to the starting mixture which would have the effect of creating these channels. It reasonably follows that in compositions where the organic fibers are not added, the number and quantity (percentage wise) of channels would simply not be present. It is also noted that although DE '585 teaches these limitations in the background section, it does not negate the fact that compositions comprising the requisite particle size, percentage porosity, and limited channel formation are old and well-known in the art. These embodiments are express teachings in the reference and are plainly stated as known compositions meeting the limitations of instant claim 1, for example. DE '585 also expressly

states it is routinely accepted that a certain proportion of micropores is indispensable for good acceptance of bone replacement material (p. 4).

Accordingly, Applicant's argument that it would not have been obvious in the art to modify the interconnecting pore size in a manner that is contrary to the express disclosure of DE '585 and that there would be no reasonable expectation of success of doing so, is plainly contradicted by the express teachings of DE '585 because DE '585 teaches that the modification of interconnecting pores is old, known, and is nothing more than routine optimization depending on the desired application (see above and page 3 of DE '585). Similarly, Applicant argues that the absence of the interconnecting macropores of DE '585 would not be effective for the intended use of DE '585 because the modification would not enable the rapid bony in-growth desired by DE '585, is without merit based on the express teachings of DE '585 at page 4, first paragraph, stating both the "indispensable" nature of micropores and also benefits for incorporating macropores (which are expressly defined as pore sizes ranging from 3-600μm in size in the prior art (p. 3) to 50-1000μm (p. 6). In comparison, micropores are taught as being in the size range of 0.5-10μm (page 5). Accordingly, DE '585 teaches pore size/pore diameter ranges of the composition expressly meeting the pore size limitations of (I), (II), and (III) of the instant claims. It is also noted that the end-points of the ranges of (I), (II), and (III) overlap, effectively producing a range of 0.5μm to 5000μm. Moreover, DE '585 expressly teaches that "[f]or suffion of the temporary bone defect filler with body fluid, it contains (read a comprises) interconnecting micropores with an average size in the range of 0.5-10μm, which make up 10-50% of the total porosity (p. 5).

Regarding Applicant's arguments that the Action provides no evidence, rationale, or reasonable expectation of success that claimed particle size is a known means for optimizing a bone growth implant, Applicant's arguments are expressly contradicted by the teachings of DE '585, as set forth above.

Regarding Applicant's arguments with regard to shape, there is no evidence of criticality of shape in the instant specification or the prior art. Changes in shape are generally a design choice. In the case of bone formation agents, alterations in shape are old and well-known in the prior art to meet the applicability of compositions for particular uses, as expressly disclosed by the cited references themselves. See also, *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (holding that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

Regarding Applicant's arguments that there is no motivation to modify or combine DE '585 and Beam (encompassing Applicant's arguments to the references individually), as stated of record, DE '585

does not teach the bone defect filler to comprise an isotropic structure. As stated of record, Beam teaches a biostructure for implantation, having bimodal pore sizes (pg 120 and claims 3 and 9), made out of tricalcium phosphate (pg 135 and claim 111), which can be treated with substances such as antibiotics, growth promoting substance, etc (Pg 134, claim 103). Furthermore Beam refers to a structure which can be isotropic (p. 10). Both DE '585 and Beam teach prior art compositions comprising bone formation composition for implantation. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). Beem need not disclose limitations taught by DE '585 or Starling.

Regarding Applicant's argument that it would technically not be possible to modify the filler of DE '585 according to Beam to achieve an isotropic structure because Beam does not disclose granules or shaped articles formed from granules having a statistically distributed porosity with the discrete pore size ranges claimed, the argument is spurious. Isotropy simply means uniformity in all directions. Applicant's claims and arguments plainly acknowledge that the claimed invention does not have "true isotropy" because the porosity is claimed as being "statistically distributed." The "statistical distribution" allows Applicant to avoid proof of express uniformity meeting the plain meaning of a uniform (isotropic) composition, such as an emulsion. The mathematics of the statistical distribution can readily vary by percentages because "statistically distributed" percentages do not accurately reflect pure uniformity, but rather only reflect statistical uniformity (i.e. averages), just as means and medians account for relativistic mathematical values of a given distribution set. In the instant case and the prior art, a mixture of granule sizes mixed together in a composition would normally create a mixture with some degree of homogeneity. When sintered, that homogeneity would be reflected in a composition comprising various pores that would be randomly distributed throughout the composition. As long as the mixture maintained some degree of homogeneity, it could be considered "statistically" isotropic – having some degree of

uniformity throughout, even though it would not approach total isotropy. Beam recognizes this fact when she discusses the isotropic nature of the embodiments in the invention at page 10. Beem expressly states that the difference in isotropy in some of the embodiments is accounted for by the interconnectedness between the microstructure, the mesostructure, and the macrostructure. Beem is merely expanding on what was taught by DE '585 in that if one of skill in the art decides to add channels, for example, by mixing in organic fibers, one would be able to change the more-or-less statistical uniformity of the composition because although he the organic fibers would be mixed in the composition, they would not be evenly distributed and oriented in the same direction or plane. This difference in orientation would create discrepancies in the overall uniformity of the composition when it is looked at on various structural levels (*i.e* micro-, meso-, and macrostructural levels). However, these issues of lack of uniformity are avoided in the preferred embodiments in Beem and in DE '585 because they don't add organic fibers to form channels in all of their embodiments and, in fact, they teach the addition of organic fibers, which form channels when sintered, as an optional step that is routine in the art as a matter of design choice. In the instant case, the composition avoids the problem of statistical uniform distribution by machining (drilling) of the composition, which can be more readily controlled than adding organic fibers to the mixture prior to sintering (compare instant claim 15).

Regarding Applicant's argument that Starling provides no suggestion that changing the pore sizes is a known means of optimizing the pore size and that there is no suggestion in Starling to modify the pore size in a manner contrary to DE '585 and that even though Starling discloses that various process steps have an effect on the pore size does not render the claimed invention obvious because Starling does not teach the desirability of modifying the pore size.. As stated above, the instant rejection is a combinatorial rejection and one individual reference need not teach what is taught by the other references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Beem and DE '585 teach the advantages of using variations and optimizations in pore sizes – to control in-growth, durability, and promote controlled, repeatable resorption characteristics using optimal parameters (p. 6 of Beem and p. 5 of DE '585).

Regarding Applicant's argument that Starling does not disclose a bone formation agent without interconnecting macropores, as stated above, Starling need not teach what is taught as optional by DE '585, above.

Regarding Applicant's argument that Starling teaches away from the claimed invention by disclosing pore sizes of 350μm to 500μm and Applicant's arguments directed to a coating taught in Starling, Applicant's argument is without merit and once again demonstrated a limited reading of the

embodiments taught by Starling. Starling expressly teaches a preferred embodiment where the microspheres range in size from about 10μm to about 100μm and a pore size range from about 0.01μm to 0.5μm with percent open porosity within Applicant's claimed range (column 8, lines 44-48. Additionally, other size and porosity values of Starling overlap those taught by DE '585 and Beem, making the combination reasonable and in line with their teachings. Moreover, Starling, Beem, and DE '585 are all drawn to the same subject matter. See, *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The coating taught in Starling is not relevant to the instant claims.

Regarding Applicant's arguments that the open porosity in Starling is limited to a single pore size in contrast to the claimed invention, having at least two discrete pore sizes, again, Applicant is arguing the references individually where the rejection is based on the combination of references. As explained above, the cited prior art references, including Starling, comprise particle sizes that expressly overlap Applicant's claimed size ranges in (I)-(III). Accordingly, The prior art teaches the limitations of the instant claims for the reasons of record and the reasons set forth herein.

4. Claims 3-4 and 11-12 and 16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29922585, Beam (WO 02/083194) and Starling et al (US 6,210,715, issued: 4/3/2001) as applied to claims 1-2, 7, 12, 13-15 and 17-20 above, and further in view of Johansson, WO 92/21302, for the reasons of record and the reasons set forth above.

Applicant argues as set forth above. Applicant argues that WO '302 does not cure the deficiencies of the other cited references for the reasons set forth in the arguments above (Remarks, p. 8).

Applicant's arguments have been fully considered, but they are not persuasive. The arguments set forth above are incorporated in the instant rejection for purposes of brevity. Johannson need not teach what is taught by the other cited references.

As stated of record, DE '585, Beem, and Starling teach all the limitations as set forth of record and above. Johansson teaches an implant made of a porous, non-toxic material with a total porosity larger than 5% but not greater than 80% by volume. The implant is characterized in that it has three distinct pore sizes: 0.1-10 μm occupy 10-80% by volume; 10-50 μm occupy not more than 5% and 50-500 μm occupy from 5-40%.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of DE '585, Beem. Starling, and Johansson because all three references teach porous implants used for bone defect fillers or bone formation agents. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). One would be motivated to combine the

references because by having porous implant with a distribution of pore sizes, one can combine a high strength and a capacity to meet high requirements as to a favorable situation for bone and tissue in-growth with an integrated interaction between soft and hard tissues, as taught, for example, by Johansson at pg 2, lines 22-26. Further, one of skill in the art would have a reasonable expectation of success because the references all expressly teach porous biostructures comprising comprise calcium phosphate for implantation that comprise a plurality of pore size distributions.

5. Claims 5, 8-10 and 18-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29922585, Beam (WO 02/083194), Starling et al (US 6,210,715, issued: 4/3/2001) and WO 92/21302 as applied to claims 3-4 and 11-12 above, and further in view of Sapieszko, US 6,521,246, for the reasons of record and the reasons set forth above.

Applicant argues as set forth above. Applicant argues that the '246 patent does not cure the deficiencies of the other cited references for the reasons set forth in the arguments above (Remarks, p. 10).

Applicant's arguments have been fully considered, but they are not persuasive. The arguments set forth above are incorporated in the instant rejection for purposes of brevity. Sapieszko need not teach what is taught by the other cited references.

As stated of record and above, DE '585, Beem, Starling, and Johansson teach as set forth above and of record. All of the references teach the bone formation agents and some of the references teach various characteristics of the granules. However, Sapieszko provides additional evidences of the characteristics of these granules.

Although there is no evidence of criticality of shape in the instant specification or the prior art as to the characteristics of the granules and changes in shape are generally a design choice Sapieszko also provides additional evidences of the characteristics of these granules in this regard. In the case of bone formation agents, alterations in shape are old and well-known in the prior art to meet the applicability of compositions for particular uses, as expressly disclosed by the cited references themselves. See also, *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (holding that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.). See also, *Tronzo v. Biomet*, 156 F.3d at 1158-59, 47 USPQ2d at 1833 (Fed. Cir. 1998) (claims to generic cup shape were not entitled to filing date of parent application which

disclosed "conical cup" in view of the disclosure of the parent application stating the advantages and importance of the conical shape); and MPEP 2144.04(B).

Sapieszko teaches inorganic shaped bodies useful for bone grafting materials, cell growth scaffolds, drug delivery and more. He also teaches the methods of producing said inorganic bodies (column 1, lines 24-28). Sapieszko also teaches that these inorganic bodies can be formed into virtually any geometric shape (column 4, lines 2-3), although a uniform one is preferable (claims 1, 14 and 22). Sapieszko also teaches that the uniform shaped body comprising meso-, micro-, and macroporous calcium phosphate, which comprises beta-tricalcium phosphate, is in the shape of a tube, block or sphere.

It would have been *prima face* obvious to one of ordinary skill in the art to combine the teachings of the cited prior art because they are drawn to compositions comprising bone formation agents that permit cell in-growth. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). One of skill in the art would be motivated the prior art reference because the embodiments of Sapieszko (beta-tricalcium and the geometric shapes of the inorganic body) teach large varieties of shaped bodies that can be widely used in surgery, laboratory, and industrial processes and one of skill in the art would know that it's obvious to modify the shape of the biostructure in order to meet the desired needs (see abstract of Sapieszko).

6. Claim 6 remains rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29922585, Beam (WO 02/083194), Starling (US 6,210,715, issued: 4/3/2001), Johansson, WO 92/21302, and Sapieszko, US 6,521,246 as applied to claims 5, 8-10 and 18-20 above, and further in view of Trisi et al (J Periodontics Restorative Dent 2003: 23:69-77), previously cited of record.

Applicant argues as set forth above. Applicant argues that Trisi does not cure the deficiencies of the other cited references for the reasons set forth in the arguments above (Remarks, p. 10).

Applicant's arguments have been fully considered, but they are not persuasive. The arguments set forth above are incorporated in the instant rejection for purposes of brevity. Trisi need not teach what is taught by the other cited references.

As stated of record, the other prior art references do expressly not teach compositions using pure beta-tricalcium phosphate. The other references are silent as to the degree of purity of the beta TCP used in the compositions taught therein. As stated of record, Trisi teaches the effect of pure phase beta-

tricalcium phosphate in bone regeneration. It teaches that pure phase beta-tricalcium phosphate is characterized by a ≥ 99 purity of the beta isomer. This material is more rapidly and predictably resorbed and replaced by newly formed bone without any residue (pg 70, paragraph 4). As stated of record, it would have been *prima face* obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings the cited references and Trisi because they are drawn to compositions comprising bone formation agents that permit cell in-growth. See, *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). One of ordinary skill in the art would have been motivated to combine the references because by using pure phase beta-tricalcium phosphate in the bone formation agent, the agent would be more rapidly resorbed and replaced by newly formed bone, therefore enhancing the function of the bone formation agent. Additionally, one of skill would expect to be successful because both teach agents used for bone formation and regeneration that comprise mainly calcium phosphate.

Conclusion

NO CLAIM IS ALLOWED.

The prior art made of record and not presently relied upon is considered pertinent to applicant's disclosure: JP-07-124241 (cited in Applicant's IDS of 8/31/2010). A machine language translation of the Japanese publication is provided.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647